510(k) Summary

JAN 12 2012

Submitter:	Edwards Lifesciences LLC
Contact Person:	Karen Jones, Senior Manager, Regulatory Affairs 12050 Lone Peak Pkwy Draper, UT 84020 (801) 565-6231
Date Prepared:	December 12, 2011
Trade Name:	Edwards Lifesciences™ Cardioplegia Delivery Sets
Classification Name:	Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting 21 CFR Part 870.4290, Product Code DTL, Class II
Predicate Device:	K892368 Cardioplegia Delivery Sets

Device Description:

Edwards Lifesciences cardioplegia delivery sets are comprised of various configurations of clear manifold connections in either straight, Y-shaped, or 4-way connections which are joined by appropriate lengths of clear, flexible tubing. Depending upon configuration, the cardioplegia delivery set may contain a vent port adapter with female luer lock, a tapered tubing adapter, tubing clamps, and/ or male and/ or female luer lock connectors.

The exterior and/ or inner-luminal cannula surfaces of product codes containing a "D" or "DII" are coated with Duraflo™ (heparin) coating.

When used on devices for cardiopulmonary surgery, the Duraflo coating improves the blood compatibility of non-biological surfaces in the extracorporeal circuit.

Each Edwards Lifesciences device is packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

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Indications for Use:

Cardioplegia Delivery Sets with and without Duraflo coating are intended for use as adapters for connecting cardioplegia administration tubing to cardioplegia delivery catheters.

Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

Comparative Analysis:

The subject devices have the same intended use and technological characteristics (i.e., design, material, chemical composition) as the predicate devices. It has been demonstrated that the subject Cardioplegia Delivery Sets are comparable to the predicate devices in fundamental scientific technology, material types, principles of operation, and functional performance evaluations. No new issues of safety or efficacy have been raised.

Functional/Safety Testing:

The functional data indicate that the Cardioplegia Delivery sets perform in a substantially equivalent manner when compared to the predicate device. The following functional tests were performed.

- Pressure vs. flow
- Clamp closure
- Kink
- Assembly tensile

All data met acceptance criteria.

Conclusion:

Testing conducted to qualify the subject changes shows that devices in this product family have met all predetermined acceptance criteria and have been shown to be safe and effective for their intended use. The subject change does not affect the intended use or alter the fundamental scientific technology of the device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 12 2012

Edwards Lifesciences LLC
c/o Ms. Karen Jones
Sr. Principal Project Manager, Regulatory Affairs
12050 Lone Peak Parkway
Draper, UT 84020

Re: K113667
Edwards Lifesciences™ Cardioplegia Delivery Sets
Regulation Number: 21 CFR 870.4290
Regulation Name: Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DTL
Dated: December 12, 2011
Received: December 13, 2011

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K113667

Device Name: Cardioplegia Delivery Sets

Indications for Use:

Cardioplegia Delivery Sets are intended for use as adapters for connecting cardioplegia administration tubing to cardioplegia delivery catheters.

Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

Prescription Use __x__ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113667

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